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IN THE

Supreme Court of the United States

October Term, 1979

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

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Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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REPLY BRIEF FOR PETITIONER INDUSTRIAL UNION DEPARTMENT, AFL-CIO

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REPLY BRIEF FOR PETITIONER INDUSTRIAL UNION DEPARTMENT, AFL-CIO

Introduction

The briefs of the industry respondents and the *amici* supporting their position (these respondents and *amici* shall hereinafter be referred to collectively as "industry") pay lip service to sustaining the lower court's statutory analysis. In Part I, *infra*, we respond to such efforts as industry makes in this direction.

The burden of industry's submissions is, however, that this case involves a regulation designed to eliminate a "*de minimis* health risk."; [1] and that "benzene exposures of

[1] Brief for Respondents (hereinafter cited as "API Br.") at 29.

10 ppm or less are unlikely to lead to any leukemia *at all.* . . ."[2] In Part II, *infra*, we show that this depiction is contrary to findings of fact made by the Secretary based on substantial evidence in the record before him. The Secretary found, based on substantial record evidence, that, absent the standard at issue here, over 30,000 workers will be exposed to unsafe levels of a carcinogenic substance, benzene, every day they go to work. In the proceedings before the Secretary, industry offered the data and other evidence it now cites to this Court to show that such exposures—between 10 ppm and 1 ppm of benzene—are safe or of *de minimis* consequence; the Secretary found, however, that industry's evidence did not support that conclusion.

I.

Industry's argument in support of the court of appeals' holding that "the Secretary cannot promulgate an occupational health standard without finding a 'reasonable[] . . . relationship between expected costs and benefits' " is a set of variations on the theme that "[u]nlike the Endangered Species Act of 1973, or the Delaney Clause of the Food, Drug, and Cosmetic Act, the OSH Act aims at relative rather than absolute protection." (API Br. 28.) We agree that OSHA does not require "absolute protection." But that undisputed proposition does not justify the lower court's holding. For Congress in different statutes has adopted a variety of non-absolutist approaches to protecting health and safety, some of which require a balancing of costs and benefits and others of which do not.[3] The protection that the Secretary is to provide to workers against toxic substances, and the factors which the Secretary must consider in promulgating a standard for exposure to such substances, must be ascertained from the langauge of OSHA and its legislative history. "The question . . . is not what a court thinks is generally appropriate to the regulatory process; it is what Congress intended for

[2] *Id.* at 16 (emphasis in original).

[3] We survey these statutes in Addendum A.

these regulations." *E. I. duPont de Nemours & Co.* v. *Train*, 430 U.S. 112, 138 (1977). Cf. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519 (1978).

1. Industry emphasizes that the "key" to our case is "the first sentence of Section 6(b)(5)." (API Br. 11). We do indeed contend that this case is governed by that sentence:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

We do so because the language and history of that sentence demonstrate that its office is to establish the extent and limit of the Secretary's authority to regulate exposure to toxic substances.

The Senate's final act prior to passing S.2193 was to rewrite that sentence. The language of § 2(b) and § 3(8)—the other provisions cited by industry to support the argument that the Act is "relative" not "absolute"—had already been settled.[4] Yet, Senator Dominick, the Nixon Administration's spokesman on the Act, continued to insist that the first sentence of § 6(b)(5) as reported out by Committee—"[t]he Secretary, in promulgating standards under this subsection, shall set the standard which most adequately and feasibly assures, on the basis of the best available evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life" (Leg. Hist. 242)—was defective in that:

[4] See IUD Br. at 27-33; Fed. Parties Br. at 42-48; and Fed. Parties Reply Br. at 19-21 for the arguments showing that these provisions considered alone do not support Industry's position.

> Any administrator responsible for enforcing the statute will be faced with an impossible choice. Either he must forbid employment in all occupations where there is any risk of injury, even if the technical state of the art could not remove the hazard, or he must ignore the mandate of Congress. . . .
>
> The confusion inherent in this provision will, in my opinion, render it no more than a hortatory admonition to the Secretary to fulfill his responsibilities under the act. * * *
>
> In trying to make this bill more palatable there is no point in putting in criteria which cannot be met. [Leg. Hist. 481-482].

The debate that ensued makes it plain that all concerned understood that the language of the first sentence of § 6(b)(5) would set the extent of the Secretary's authority to regulate toxic substances.

The modification of that sentence "agreeable to all" adopted at the conclusion of that debate solved the problem Senator Dominick had identified, as he stated:

> Unfortunately, we had language providing that anyone would be assured that no one would have a hazard, . . . no one would have any problem for the rest of his working life.
>
> It was an unrealistic standard. [Leg. Hist. 502].

The statutory words chosen, on their face, state that the Secretary is to set levels of protection possible to achieve, not those that are perfect in theory but impossible of achievement.[5] And, that reading of the language is consistent with Senator Dominick's earlier statement of his conception of the proper role of the Secretary in setting standards:

> The duty to set standards and produce criteria for standards implies that the criteria and the standards will be as effective as possible; not that they will produce a perfect environment. No human effort can produce a perfect environment no matter how hard we try. [Leg. Hist. 376.]

There is not a word in the debate suggesting that the Senate intended to require the Secretary to balance costs and benefits.[6] Given that the term "feasibility" does not in common parlance connote a cost-benefit evaluation, and that Congress has in numerous instances treated feasibility and cost-benefit evaluation as discrete concepts, "the silence of [Congress] . . . is pregnant with significance." Cf. *Labor Board* v. *Fruit Packers*, 377 U.S. 58, 66-67 (1964).[7]

2. It is inherently unlikely that the second and third sentences of § 6(b)(5), which were adopted in Committee, inform a proper understanding of the amendment to the first sentence, which was adopted on the Senate floor to clarify what the Committee bill meant. And in fact, the latter two sentences do not alter the substantive criteria for toxic substance standards contained in the first sentence; those sentences merely set forth the types of evidence the Secretary is to employ in carrying out the mandate of the first sentence—types of evidence which include not only "research, demonstrations, [and] experiments," but also "such other information as may be appropriate."

The House, whose bill did not set forth any criteria governing the Secretary's standard-setting authority, ac-

[5] For a more complete discussion of the legislative history of the first sentence of §6(b)(5), see our opening brief at pp. 13-23. Industry, rather than focus on this critical point in the genesis of §6(b)(5), contends that Congress' intention in using the word "feasible" should instead be discerned from a statement which accompanied the introduction of the Administration's original proposed occupational safety and health bill in a prior Congress. API Br. at 42-43, 9b. Industry mistakenly attributes that statement to Senator Javits, misconstrues its import, and ignores Senator Javits' reservations as to the merit of the Administration bill. See Fed. Parties Reply Br. at 22-23, n. 17.

[6] See Fed. Parties Reply Br. at 24-26 for a demonstration of the irrelevance to the issue here of the substitution of the word "material" for "any" which occurred in the same amendment to §6(b)(5) described in the text.

[7] For examples of statutes in which Congress has treated feasibility and cost-benefit evaluation as discrete concepts see Addendum A to this brief.

cepted §6(b)(5) as passed by the Senate. To be sure as industry points out, the Conferees altered the Senate bill by adopting §6(f) which provides that the Secretary's findings are to be supported by "substantial evidence on the record as a whole." The Conferees did not suggest that §6(f) modifies the Act's substantive provisions and we cannot discern the logic of industry's implication that it does so.

3. It is decisive that industry's argument that the Secretary is required to balance costs and benefits lacks a statutory predicate. But out of caution we pause to note the defects in industry's policy justification for its position—*viz.* that such an inquiry must be undertaken so that the

> finite * * * * societal resources that can be devoted to these health and safety risks * * * [are] allocate[d] . . . where they can be expected to do the most good.[8]

The "logic" of this justification requires that the Secretary, before he can promulgate a standard to protect employees against any health hazard, must inventory all other hazards possibly faced by those employees and then compare the relative costs and benefits of the proposed standard with the costs and benefits of regulating each of the other possible hazards. And industry would read the Act to require the Secretary to embark on that task despite the recognition by the sponsors that:

> In the field of occupational health * * * [there is a] lack of information and records, * * *
>
> * * * [M]aterials long in industrial use are only now being discovered to have toxic effects. * * * [T]echnological advances and new processes in American industry have brought numerous new hazards to the workplace. * * * It is estimated that every 20 minutes a new and potentially toxic chemical is introduced into industry. New processes and new sources of energy present occupational health problems of unprecedented complexity.

[8] API Br. at 29, 27, 73; see also id. at 5, 18-20, 25, 32-33, 35, 58-59, 63, 66, 72, 78, 80; and Addendum C at 2c, 7c. See also Brief for *Amicus* Chamber of Commerce (hereinafter "Chamber Br.").

> Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others.[9]

Nevertheless under industry's construct, to do anything the Secretary would have to investigate and evaluate everything. This in the name of "common sense" and "pragmatism." See API Br. 5, 29.

II.

In our opening brief, at 8-11, we set forth the Secretary's nine critical findings which form the predicate for the promulgation of the benzene standard. None of those findings was upset by the court below. Those findings negate any contention that the health risk sought to be reduced by the standard is either non-existent or *de minimis*: exposure to airborne benzene causes leukemia and other serious and sometimes fatal diseases; hundreds of employees in this country have died of leukemia from occupational exposure to airborne benzene; without the standard, over 30,000 employees in this country will regularly be exposed to airborne benzene at their workplaces at levels in excess of 1 ppm; there is no level of exposure to benzene which can be considered safe in terms of benzene's leukemogenic effect; a decrease in the exposure level to benzene will result in a decreased risk of leukemia; and, there is no way to quantify the number of leukemia deaths that would result if the standard is not put into effect, let alone to conclude that that number would be zero or *de minimis*.

In making these findings, the Secretary considered evidence submitted by industry in support of the contention that there is no health risk posed by regular exposure to benzene at levels of 10 ppm and below. The Secretary, after reviewing the entire record, including the cross-examination of industry's witnesses, found that industry's evidence does

[9] S. Rep. No. 91-1282, 91st Cong., 2d Sess. 2-3 (1970), Leg. Hist. 142-143.

not support its contention. In this Court, industry in effect resubmits that same evidence. First, industry refuses to accept that the Secretary found, based on ample record evidence, that there is no safe level of exposure to airborne benzene. Second, industry ignores that the Secretary found, again based on ample record evidence, that there is no way to quantify the number of lives that will be saved by the standard. Given the weight industry places on the assertion that the standard does not add to the protection afforded the employees covered, we turn now to the substantial evidence that supports the Secretary's contrary conclusion.

A. The Secretary's finding that there is no level of exposure to benzene which can be considered safe is supported by substantial evidence in the record.

In the proceeding before the Secretary, it was undisputed that exposure to airborne benzene causes leukemia; studies had reported the incidence of leukemia among workers exposed to high levels of benzene for varying lengths of time to be as much as a twenty times greater than the incidence among the general population. Pet. App. 100a. There was considerable dispute, however, on the question whether a safe level of exposure to benzene could be identified. A number of eminent medical scientists—*inter alia*, Dr. Muzaffer Aksoy of Instanbul University (Ex. 60 at 12-13; Tr. 148-149); Dr. Marvin Sakol (Tr. 328); Dr. Bernard Goldstein of the New York University Medical Center (Ex. 75 at 2; Tr. 351-352); Dr. Peter Infante of the National Institute for Occupational Safety and Health ("NIOSH") (Tr. 895); and Dr. Robert Laigo of NIOSH (Tr. 1229)—testified that, on the basis of the current state of medical and scientific knowledge relating to benzene, exposure to benzene must be considered unsafe at all levels. NIOSH, the research arm created by the Act to provide the Secretary expert assistance in standard setting,[10] also went on record in support of the proposition that no level of exposure to benzene can be considered safe. Ex. 2.5 at 6; Tr. 745-746.[11] Indeed, on the basis of its analysis of the scientific evidence concerning the risks posed by benzene, NIOSH had "strongly recommend[ed]" in 1976 that the Secretary immediately promulgate an emergency temporary standard reducing permissible exposures to 1 ppm. Pet. App. 72a; Ex. 2-6 at 1; see also Ex. 2-5 at 1, 6.

[10] Section 22(a) of the Act, 29 U.S.C. § 671(a).

In view of this testimony, industry's assertion that the Secretary's no-safe-level finding rested solely on a "regulatory 'policy assumption,'" rather than on a "factual basis" is wrong.[12] While the issue could not be resolved by empirical evidence, the expert scientific testimony upon which the Secretary relied constitutes substantial evidence in support of his determination. As this Court has repeatedly held,

> well-reasoned expert testimony—based on what is known and uncontradicted by empirical evidence—may in and of itself be "substantial evidence" when first-hand evidence on the question . . . is unavailable. This proposition has been so long accepted, . . . that we do not consider it fairly in dispute.

FPC v. Florida Power & Light Co., 404 U.S. 453, 464-466 (1972). The Court in that case went on to quote from an opinion by Judge Parker in *United States ex rel. Chapman v. FPC*, 191 F.2d 796, 808 (4th Cir. 1951), aff'd, 345 U.S. 153 (1953), the following passage which has application here as well:

> The [substantial-evidence] rule is no different because

[11] The Secretary's no-safe-level determination was also supported by extensive record evidence regarding carcinogens in general. See, e.g., the Report to the Surgeon General by the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens of the National Cancer Institute (Ex. 272 at 1); the views of the Committee on Public Information in the Prevention of Occupational Cancer of the National Academy of Sciences (reported in Ex. 76 at 4); and the testimony of Dr. Herman Kraybill of the National Cancer Institute (Tr. 1210) and of Dr. Charles Shaw, a cancer researcher at the M. D. Anderson Hospital and Tumor Institute (Tr. 140). See also Ex. 97 at 55.

[12] API Br. at 16, and n. 38.

the questions involve matters of scientific knowledge and the evidence consists largely of the opinion of experts. The court may not, for that reason, ignore the conclusions of the experts and the Commission and put itself in the absurd position of substituting its judgment for theirs on controverted matters of [science]. It is in just such matters that the findings of the Commission, because of its experience and the assistance of its technical staff, should be accorded the greatest weight and the courts should be hesitant to substitute their judgment for that of the Commission.[13]

B. The Secretary's finding that there is no way to estimate the number of lives that will be saved by the standard is supported by substantial evidence in the record.

There is no direct empirical data documenting the extent of the risk of leukemia for employees exposed to airborne

[13] Industry appears to suggest that by eliminating language which would have allowed standards to be issued on the basis of "views and arguments," Congress meant to preclude the Secretary from relying on expert scientific opinions. But industry misapprehends the nature of Congress' concern regarding that language.

The "views and arguments" provision appeared in the Daniels bill as reported out of the House Committee (Leg. Hist. 728-730), and in the Williams bill (S. 2193) as originally introduced (Leg. Hist. 6-7). It stated: "Upon the entire record before him, including . . . any evidence, data views and arguments submitted in connection with the hearing, the Secretary shall . . . issue a rule. . . ." (Leg. Hist. 7, 730). The provision was deleted from the Williams bill by the Senate Committee, without discussion, see S. Rep. No. 91-1282, 91st Cong., 2d Sess. (1970), Leg. Hist. 141 *et seq.* In lieu of the Daniels bill, the House passed the Steiger-Sikes substitute bill, which did not specify the basis upon which standards were to be promulgated, but which listed "views or arguments" among the matters which interested parties could submit to the standard-setting agency. See Leg. Hist. 1120-1122. The Conference Committee adopted the Senate provision without any discussion of the "views and arguments" language contained in the House provision. See H.R. Rep. No. 91-1765, 91st Cong., 2d Sess. 35 (1970), Leg. Hist. 1188. Only one statement in the legislative history cited by industry actually bears on the "views and arguments" provision; it is found in the "Additional Minority Views" expressed in the House Report. See H.R. Rep. No. 91-2191, 91st Cong., 2d Sess. 53, 54 (1970), Leg. Hist. 883, 884. That statement refutes industry's theory as to why the provision was revised.

Under the heading "Full Protection of the Administrative Procedures Act Denied," the authors of the minority views stated that by allowing standards to be based "upon 'views and arguments' rather than solely on probative evidence," the Committee bill "depart[ed] from the provisions of the APA" and "deviat[ed] from regular and fair procedures." *Ibid.* They protested that "[t]he requirements that administrative decisions be based upon facts and sound reasons mean little when a loophole of this type is included in a statute." *Ibid.*

As we have shown in the text, it has long been settled that an agency subject to a substantial evidence test may properly base its regulations on expert scientific opinions. It is therefore plain that the authors of the minority views were not suggesting that the Secretary could not consider evidence of this sort. Rather, the fair reading is that the authors of the minority views feared that the unusual reference to "views and arguments" in the Committee bill would permit the Secretary to base a standard on nothing more than the mere arguments of interested parties.

benzene at or below the level of 10 ppm. The absence of such direct data is not attributable to any failure on the Secretary's part. The latency period for benzene-induced leukemia can span a period of twenty years or more. Pet. App. 182a. Consequently, a valid study of actual case histories (an epidemiologic study) must examine benzene exposures which occurred many years in the past. As the Secretary explained, "it is extremely difficult to reconstruct and define employee exposures retrospectively." Pet. App. 182a. Moreover, exposures from that long ago were in general "most certainly . . . at higher concentrations than present levels." *Ibid.* See Tr. 2556-2557, 2667. Thus, the Secretary found that there was an absence "of an adequate size cohort of workers exposed to benzene less than 10 ppm and who have been followed for an adequate amount of time." Pet. App. 182a-183a.[14]

Lacking any direct data showing actual experience with

[14] See Addendum B to this brief for a discussion of the evidence supporting the Secretary's rejection of industry's contention that certain epidemiologic studies demonstrate an absence of leukemia risk from benzene exposures of 10 ppm or below.

benzene exposures at 10 ppm and below, the Secretary considered whether he could utilize the results of studies in the record involving exposure to higher concentrations of benzene to estimate how many lives would be at risk at exposure levels of 10 ppm and below. The Secretary concluded that "there does not exist an adequate scientific basis for establishing the quantitative dose-response relationship between exposure to benzene and the induction of leukemia and other blood diseases." Pet. App. 160a. He reached that conclusion for two reasons.

First, the predicate for estimating unknown quantities from known quantities is that there must first be a known quantity. But the Secretary found "uncertainty in . . . the actual magnitude of expected deaths" attributable to any level of exposure. Pet. App. 160a. The available epidemiologic data showing the leukemogenic effects of benzene exposures at levels thought to be in excess of 10 ppm do not show the *level* and *duration* of exposure of the cases studied, and the data understate, to a degree which cannot be determined, the number of leukemia deaths resulting from such exposure.[15] As Dr. Herman Kraybill of the National Cancer Institute testified, he along with other scientists had attempted to develop a dose-response curve for benzene, but had abandoned the effort due to the lack of necessary data. Tr. 760-761, 776. In Dr. Kraybill's words (Tr. 760-761):

> . . . [W]e like to estimate risk factors. This has been done, as many of you recall, with vinyl chloride several years ago.
>
> . . . [T]o estimate the risk factors on experimental data, . . . presupposes [that] you have good toxicity data. When I say toxicity data, I mean good dose-response data[. For] vinyl chloride . . . indeed we did have that.
>
> But with benzene, it appeared that we didn't have this situation, so therefore, most of us gave up. . . .
>
> • • • •
>
> With benezene, we sort of struck out.[16]

Second, even if the existing studies could have provided a starting point, the Secretary found that there is no satisfactory theory of extrapolation from known carcinogenic effects of a substance at high exposure levels to projected carcinogenic effects of the substance at lower exposure levels. Pet. App. 160a. As Dr. Richard Wilson, upon whose testimony industry places such great reliance, grudgingly acknowledged (App. 93):

> It is conceivable, I suppose, that any dose-response curve is possible. . . . It would be a rather unusual, almost I think, revolutionary contribution to the literature on cancer to have a dose-response curve on cancer.

See also, McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 Geo.L.J. 729, 736 n. 27 (1979); Addendum C at 8c-9c.[17]

In the face of these findings, industry continues to cite

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[15] Further, the Secretary found that genetic, environmental and other factors produce variations in the susceptibility of individuals to benzene-induced leukemia. Pet. App. 184a. Consequently, there is no assurance that the incidence of benzene-leukemia found in any study of a particular group of employees accurately represents the incidence which would occur in the general population.

[16] Dr. Bernard Goldstein of the New York University Medical Center testified to the same effect (Tr. 360):

> We don't have information that I would say would be good to give us a relation between any levels of benzene and leukemia. I just don't think that one can take this type of data and say that, "Well, let's see, we got nothing at 50; we got something at 40; we got nothing at 60." The literature just is not conducive to that type of analysis.

The testimony of Dr. Charles Shaw of the M. D. Anderson Hospital and Tumor Institute was in accord (Tr. 415). See also the testimony of Dr. Infante, Tr. 1055-1056, 1156.

[17] Industry nevertheless maintains that a meaningful "risk assessment" could be prepared by making "conservative assumptions" at each point of uncertainty, so as to arrive at an "upper-bound" estimate of the risk. See API Br. at 20; Chamber Br. at

as if it were gospel an extrapolation submitted by Dr. Wilson based on selected epidemiologic data in the record. It is upon this extrapolation that industry largely bases its claim that the health risk regulated by the Secretary is non-existent or *de minimis*. In addition to the Secretary's general findings that such extrapolations are invalid, the Secretary specifically considered and rejected Dr. Wilson's extrapolation. Pet. App. 161a-162a. We show in Addendum C to this brief the particular factors which support the Secretary's rejection of Dr. Wilson's analysis.

10-12. But as we show more fully in Addendum C, given the gaps in the existing data, the uncertainties which confront any effort to estimate the extent of the risks posed by low-level benzene exposures are so great that the range of possible assumptions is literally infinite; "[t]he choice of assumptions under these conditions of uncertainty transcends the domain of science." Lovins, *Cost-Risk-Benefit Assessments in Energy Policy*, 45 Geo. Wash. L. Rev. 911, 924 (1977). Even if the range of uncertainty were narrower, industry's notion that truly "conservative" assumptions can be identified is mistaken. "Conservative assessments embody value judgments in a not clearly identifiable way * * * * [The] problem with the conservatism argument is that there is no place at which it can stop * * * * In practice of course, people do stop, but then it becomes difficult to understand what they mean by being conservative." Cornfield, *Carcinogenic Risk Assessment*, 198 Science 693, 695-696 (1977).

Industry contends that various public and private bodies have endorsed the use of risk assessments based on "conservative assumptions" in a number of regulatory contexts. But that contention sheds no light on how *this* statute should be construed and administered. However, lest the Court be left with a false impression that unanimity exists with respect to the role of risk assessments in regulatory policy, we note simply that this matter is presently a subject of substantial political debate. See generally Baram, *Regulation of Health, Safety and Environmental Quality and the Use of Cost-Benefit Analysis*, Final Report to the Administrative Conference of the United States, March 1, 1979 at 19-45. For example, a Congressional committee has stated that "[t]he limitations on the usefulness of benefit/cost analysis in the context of health, safety, and environmental regulatory decision-making are so severe that they militate against its use altogether." House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, *Federal Regulation and Regulatory Reform*, 95th Cong., 1st Sess. 515 (1976).

C. This case involves a regulation to protect more than 30,000 workers from a risk of potentially great; albeit unknowable, dimensions.

The upshot of the Secretary's findings, based on the best available evidence, is that the leukemia risk posed by employee exposure to benzene at levels of 10 ppm or below is potentially great, albeit unknowable. The Secretary rejected industry's contention that the risk is non-existent or *de minimis;* and the Secretary's assessment of the nature of the risk to which the benzene standard is directed, being firmly grounded in the record evidence, is conclusive. *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 791 (1969).[18]

Industry asserts nevertheless that the court below adopted its characterization of the health risk at issue here. The Secretary in his Statement said: "While the actual estimation of the number of cancers to be prevented [by the standard] is highly uncertain, the evidence shows that the number may be appreciable." Pet. App. 160a. The court of appeals, in considering whether the Secretary had demonstrated sufficient benefits from the standard to satisfy a cost-benefit evaluation, stated as follows (Pet. App. 17a, 18a):

> OSHA merely assumed that benefits from the reduction "may be appreciable."
>
> • • •
>
> This justification is deficient in one crucial way: substantial evidence does not support OSHA's conclusion that benefits are *likely* to be appreciable. Without an estimate of benefits supported by substantial evidence, OSHA is unable to justify a finding that the benefits to be realized from the standard bear a reasonable relationship to its one-half billion dollar price tag.

(Emphasis added).

[18] Cf. also *Radio Corp.* v. *United States*, 314 U.S. 412, 419-420 (1951); *Permian Basin Area Rate Cases*, 390 U.S. 747, 766-767 (1968).

Industry implies that the court of appeals thus found that the benefits of the standard are non-existent or *de minimis*. But in context the court's words bear a quite different meaning. The court's conclusion was not that the benefits of the standard are in fact non-existent or *de minimis*, but that the Secretary had not demonstrated by what the court deemed appropriate evidence that the benefits of the standard would justify its costs. As the court went on to explain (Pet. App. 18a-19a):

> Th[e] finding and deduction [that the standard will result in some benefit], however, does not yield the conclusion that measurable benefits will result, and OSHA is unable to point to any *studies or projections* supporting such a finding. . . . The lack of substantial evidence of discernible benefits is highlighted when one considers that OSHA is unable to point to any *empirical evidence* documenting a leukemia risk at 10 ppm even though that has been the permissible exposure limit since 1971. OSHA's assertion that benefits from reducing the permissible exposure limit from 10 ppm to 1 ppm are likely to be appreciable, an assumption based only on inferences drawn from studies involving much higher exposure levels *rather than on studies involving these levels or sound statistical projections from the high-level studies,* does not satisfy the reasonably necessary requirement limiting OSHA's action.

(Emphasis added). See also Pet. App. 33a.

The court, then, did not overturn the Secretary's conclusion that the health risk addressed by the standard is potentially great, albeit unknowable—i.e., that the "number of cancers to be prevented" though "uncertain . . . may be appreciable." Pet. App. 160a. Rather, the court construed the Act to foreclose the Secretary from issuing a regulation to protect employees from that risk until empirical "studies or projections" establish that the risk is in fact of sufficient magnitude to justify the costs of the standard. In the court's words, "[u]ntil such estimates are possible, OSHA does not have sufficient information" to regulate. Pet. App. 21a.

As we have shown, the Secretary found that the existing epidemiologic data are inadequate to serve as a basis for an extrapolation of the leukemia risk at benzene exposure levels of 10 ppm or below. There is no basis in the record for supposing that this inadequacy may be overcome by any means short of awaiting the experience of long-term exposures to benzene at the levels—i.e., 10 ppm and below—permitted by the standard which the Secretary sought to replace. Thus, notwithstanding the court's disclaimer, it may well be that the consequence of its ruling is that "OSHA must wait until deaths occur as a result of exposure at levels below 10 ppm before it may validly promulgate a standard reducing the permissible exposure limit." Pet. App. 20a. See our opening brief at 27-28, nn. 27-28.

The court said that the Secretary "must regulate on the basis of what is known rather than on the basis of what is unknown." Pet. App. 20a. So, indeed, he must. But as Socrates taught long ago, the highest knowledge is knowing the limits of our own knowledge. That lesson has special force where, as here, the inquiry is at the "frontiers of scientific knowledge." *IUD* v. *Hodgson*, 499 F.2d 467, 474 (D.C. Cir. 1974). The Secretary's instant determination was based not, as the court of appeals would have it, on arbitrary "assumptions," but, in precise accord with the third sentence of §6(b)(5), on the best scientific evidence available—evidence concerning both what is known and what is not known about benzene as a carcinogen. "Under the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient." *Society of the Plastics Indus., Inc.* v. *OSHA*, 509 F.2d 1301, 1308 (2d Cir. 1974), *cert. denied*, 421 U.S. 992 (1975).

CONCLUSION

For the reasons stated herein and in our opening brief, the decision of the Fifth Circuit should be reversed insofar as it invalidates the reduction in the permissible exposure limit and the provisions related thereto.

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ADDENDUM A

A Survey of "Non-Absolutist" Statutory Approaches to Protecting Health and Safety

Balancing of costs and benefits is expressly required by several regulatory statutes. An early example is the Flood Control Act of 1936, 33 U.S.C. § 701(a): "[T]he Federal Government should improve or participate in the improvement of navigable waters . . . for flood-control purposes if the benefits to whomsoever they accrue are in excess of the estimated costs and if the lives and social security of people are otherwise adversely affected." More recent examples include two statutes in which Congress has provided that in addition to being "feasible," regulations promulgated under the statute should reflect a balancing of costs and benefits. The Outer Continental Shelf Lands Act Amendments of 1978, 43 U.S.C. § 1347(b), provide that offshore drilling operations shall use "the best available and safest technologies which the Secretary determines to be economically feasible, . . . except where the Secretary determines that the incremental benefits are clearly insufficient to justify the incremental costs of utilizing such technologies." The Energy Policy and Conservation Act of 1975, 42 U.S.C. § 6295 (a) (4) (D), provides that energy efficiency standards promulgated for certain products must not only be "economically feasible," but must, in addition, be such that "the savings in operating costs . . . outweigh" the adverse effects of the standard.

In several instances, Congress has required some form of cost-benefit balancing with respect to the promulgation of certain regulations under a statute, while requiring other regulations under the same statute to be developed without regard to any such balancing, albeit with some consideration of costs. A good example is the Federal Water Pollution Control Act Amendments of 1972, as amended, 33 U.S.C. § 1251 *et seq.*

That statute specifies that in setting effluent limitations to be achieved by 1977, the Environmental Protection

Agency ("EPA") is to require the use of the "best practicable control technology currently available (§ 1311 (b)(1)), and the statute further provides that EPA's "assessment of [that] technology shall include consideration of the total cost of application of technology in relation to the effluent reduction benefits to be achieved from that application. . . ." (§ 1314 (b)(1)(B)). The latter requirement entails a "limited cost-benefit analysis"— a "balancing test between total cost and effluent reduction benefits [which] is intended to limit the application of technology only where the additional degree of effluent reduction is wholly out of proportion to the costs of achieving such marginal level of reduction. . . ." 118 Cong. Rec. 33696 (1972), discussed in *E. I. duPont de Nemours & Co.* v. *Train*, 430 U.S. 112, 129-130 (1977).

On the other hand, the 1972 Amendments provide that effluent limitations to be attained by 1983 should be based on "the best available technology economically achieveable" (as amended, § 1311 (b)(2)(A)), and under that provision, while costs are to be considered, "no balancing test will be required." 118 Cong. Rec. 33696 (1972). See *Weyerhaeuser Corp.* v. *Costle*, 590 F.2d 1011, 1044-1046 (D.C. Cir. 1978).

The amendments also authorize EPA to set more stringent effluent limitations for particular sources of pollution where the generally mandated levels will not achieve the required standard of water quality in a particular setting; but before so doing the Administrator must conduct a public hearing to assess the "economic and social" costs and benefits involved (33 U.S.C. § 1312 (b)(1)), and the more stringent limitations cannot be applied against any person who demonstrates at that hearing that "there is no reasonable relationship between the economic and social costs and the benefits to be obtained. . . ." 33 U.S.C. § 1312 (b)(2).

Similarly, the Clean Water Act of 1977, 33 U.S.C. § 1251 *et seq.*, which established new criteria for the regulation of "conventional pollutants," requires that in setting effluent limitations for such substances EPA shall consider "the reasonableness of the relationship between the costs of attaining a reduction in effluents and the effluent reduction benefits derived. . . ." 33 U.S.C. § 1314 (b)(4)(B).

Another statute which requires cost-benefit evaluations for some regulations but not others is the Clean Air Act Amendments of 1970, as amended, 42 U.S.C. § 7401 *et seq.*, which were passed the same week as OSHA. In that statute, the provision which authorizes EPA to prohibit the manufacture or sale of a fuel or fuel additive that significantly impairs an emission control device expressly requires EPA to perform "a cost benefit analysis" (42 U.S.C. §7545f-6c(c)(2)(B), while the provision which authorizes the prohibition of a fuel or additive that would "endanger the public health or welfare" contains no such requirement (42 U.S.C. § 7545f-6c (c)(2)(A)).

Another "non-absolutist" approach to health and safety regulation, requiring a particular form of cost-benefit balancing, has been adopted by Congress in the several statutes which are based on the concept of "unreasonable risk."

One of the first "unreasonable risk" provisions is contained in the National Traffic and Motor Vehicle Safety Act of 1966, as amended, 15 U.S.C. §1391(1). "As the Senate hearings make clear, the word 'unreasonable' was placed in the bill deliberately, to signify a 'common-sense' balancing of safety benefits and economic cost." *United States* v. *General Motors Corp.*, 518 F.2d 420, 435 (D.C. Cir. 1975). See S.Rep. No. 89-1301, 89th Cong., 2d Sess. 6 (1966).

The year before OSHA was enacted, Congress incorporated an "unreasonable risk" requirement in the Child Protection and Toy Safety Act of 1969, as amended, 15 U.S.C. § 1261(s). The provision was included so as to require consideration of "such factors as the utility of the object, the degree of danger it presents, and the feasibility of designing out that danger." S.Rep. No. 91-237, 91st Cong., 1st Sess. 7 (1969). See generally *Forester* v. *CPSC*, 559 F.2d 774, 789 (D.C. Cir. 1977).

Two years after OSHA was enacted, Congress adopted an "unreasonable risk" requirement in two more statutes. In incorporating that concept in the Consumer Product Safety Act of 1972, Congress stated:

> Protection against unreasonable risks is central to many Federal and State safety statutes and the courts have had broad experience in interpreting the term's meaning and application. It is generally expected that the determination of unreasonable hazard will involve the Commission in balancing the probability that risk will result in harm and the gravity of such harm against the effect on the product's utility, cost and availability to the consumer.

H.R. Rep. No. 92-1153, 92d Cong., 2d Sess. 33 (1972). See also S. Rep. No. 92-749, 92d Cong., 2d Sess. 6, 14-15 (1972). We discussed the pertinent provisions of the Consumer Product Safety Act in our opening brief at pp. 30-33. Similarly, in the Federal Environmental Pesticide Control Act of 1972, as amended, 7 U.S.C. § 136(bb), Congress defined the term "unreasonable adverse effects on the environment" to mean "an unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." The EPA may regulate a pesticide only to the extent that the pesticide entails such "unreasonable adverse effects." See 7 U.S.C. §§ 136a(c)(5)(C), (D), 136a(c)(7), (8), 136a(d), 136d(b). This explicitly requires a balancing of costs and benefits. See *Environmental Defense Fund* v. *EPA*, 548 F.2d 998, 1005 (D.C. Cir. 1976).

Recently, Congress enacted yet another statute based on the concept of "unreasonable risk" and explicitly requiring a balancing of costs and benefits: the Toxic Substances Control Act of 1976, 15 U.S.C. § 2605(a), (c)(1).

Finally, the provisions of the Federal Food, Drug, and Cosmetic Act concerning human and animal drugs, 21 U.S.C. §§ 321(p)(1), 360b, illustrate an altogether different "non-absolutist" approach. In determining whether a human drug is "safe" the Food and Drug Administration

("FDA") must assess whether "the expected therapeutic gain [from the drug] justifies the risk entailed by its use." *United States* v. *Rutherford*, —— U.S. ——, 47 U.S.L.W. 4724, 4727 (June 8, 1979). That is to say, a drug is "safe" only if its curative benefits outweigh its side effects. But while the statute requires a balancing of *therapeutic* costs and benefits, it does not contemplate a balancing of *economic* costs and benefits. See Decision of the Commissioner in the Matter of Diethylstilbestrol: Withdrawal of Approval of New Animal Drug Applications, 44 Fed. Reg. 54852, 54881-54883 (Sept. 21, 1979). On the other hand, the provisions of the Food, Drug, and Cosmetic Act which authorize FDA to set "tolerances" for certain hazardous substances (e.g., 21 U.S.C. §§ 346, 346a, 348(c)(4)(A), (B)) may contemplate some form of economic cost-benefit balancing. *Id.* at 54881-54882.

ADDENDUM B

An Analysis of the Basis for the Secretary's Rejection of Industry's Contention That Epidemologic Studies Have Shown Benzene to Be Safe at Low Levels of Exposure

In its attempt to portray the risks arising from exposure to benzene at concentrations of 10 ppm and below as nonexistent or *de minimis*, industry relies on a group of epidemiologic studies which the industry respondents cited first to the Secretary and then to the court below in their effort to demonstrate that a safe "threshold" level of exposure exists for benzene. API Br. at 14-17. See pp. 8-10. of the reply brief, *supra*. The Secretary expressly rejected industry's contentions regarding the conclusions which can be drawn from the studies, and the court of appeals did not upset the Secretary's determinations. Undaunted, industry now offers its theories regarding those studies to this Court, as if those theories were fact.

Industry advances two arguments regarding the epidemiologic data. First, industry claims "it was shown that when benzene exposures were reduced below 100 ppm—*but not eliminated*—the excess incidence of leukemia found in the principal studies cited by OSHA (the reports of Drs. Infante, Aksoy and Vigliani) *ceased to occur.*" API Br. at 14 (emphasis in original). Second, industry asserts that "this [purported] evidence that low-level benzene exposures present no significant risk of leukemia was bolstered by a series of epidemiologic studies of hundreds of thousands of workers exposed to low concentrations of benzene" which, according to industry, "all failed to uncover any excess incidence of leukemia. . . ." API Br. at 14-15. (These latter studies are referred to as the "negative studies.")

In this Addendum, we show that industry's representations regarding the epidemiologic studies—which are "supported" by little more than citations to the arguments presented in the briefs filed by the industry respondents

before the Secretary—seriously distort the facts as found by the Secretary and as established by the record. As we show, the Secretary correctly found that the epidemiologic studies lend no support to industry's contention that the risks posed by worker exposure to benzene at concentrations of 10 ppm and below are nonexistent or *de minimis*.

I. The Aksoy, Vigliani and Infante Studies

Industry maintains that the data assembled by Dr. Aksoy and Dr. Vigliani, which demonstrate a risk of leukemia at certain exposure levels, show that "when benzene exposures were reduced below 100 ppm—*but not eliminated*—the excess of leukemia found in the . . . studies . . . *ceased to occur*" API Br at 14 (emphasis in original). Although industry makes this representation as if it were an undisputed fact, in reality industry's view of the data is directly contrary not only to the findings of the Secretary regarding this data, but to the statements of Dr. Aksoy and Dr. Vigliani as well.

Industry's view of the Aksoy and Vigliani data is premised on the assumption that when the use of high-benzene solvents ceased in the workplaces studied by Drs. Aksoy and Vigliani, the solvents which were substituted continued to contain substantial amounts of benzene. But Dr. Aksoy stated that "[t]he substitutes for benzene in the workplaces studied were analyzed by gas chromatography . . . The results showed that the substitutes contained *no benzene.*" Ex. 60 at 3 (emphasis added). See also Tr. 2567 (testimony of Dr. Irving Tabershaw). Similarly, Dr. Vigliani wrote that no new cases of leukemia were reported in the workplaces he studied after "the replacement of benzene with toulene" (Ex. 2.15 at 125); and the Secretary found that Dr. Vigliani's data demonstrate that "toulene and benzene are '. . . quite different chemical entities from toxicological and pharmacological points of view' and that, 'toulene *free from benzene* can be safely used in industry as a suitable solvent *in replacement of benzene.*'" Pet. App. 101a (emphasis added).

Thus, as the Secretary found, the Aksoy and Vigliani data show that the excess leukemia incidence in the populations in question ended when exposures to benzene had been *eliminated*—not, as industry would have it, when exposures had been reduced to low levels. Pet. App. 100a-102a. The court of appeals did not disagree with that conclusion. See Pet. App. 8a, n. 13.

Industry's interpretation of the Infante study is as far-fetched as its view of the Aksoy and Vigliani studies. Industry makes much of the fact that while Dr. Infante's study found a large excess incidence of leukemia among a group of workers who had been exposed to benzene in the 1940's, a study by University of North Carolina ("UNC") researchers involving workers employed at a later date in one of the Pliofilm operations which had been studied by Dr. Infante did not uncover any excess incidence of leukemia. API Br. at 14, citing Ex. 187.B-13. Industry contends that this divergence results from the fact that exposures in the plant were probably lower during the time period studied by these researchers than during the time period studied by Dr. Infante. But the number of Pliofilm workers studied by UNC was so small that the study involved only 18 deaths from any cause among those workers. Ex. 187.B-13, Table 1, p. 9.[1] In the general population, only about .75 percent of deaths are from leukemia. See Tr. 2791-2792. Consequently, out of 18 deaths in the general population, the predicted number of leukemia deaths would be 0.13. Thus, one would not expect to find a leukemia death among the workers studied by UNC even if those workers were subjected to a risk factor much higher than that of the general population. As Dr. Infante testified with respect to a similar study involving the same plants:

> "[W]hen you are expecting less than one case, and . . . you observe none, . . . to make any kind of scientific

[1] Table 1 shows that 18 deaths due to all causes were observed in "Occupational Title Group 19." Group 19 is the Pliofilm area, see Ex. 187.B-13 at 8, 40.

statement . . . even about absence of risk on those numbers would, to me, be entirely misleading. (Tr. 1079-1080).[2]

II. The "Negative Studies"

Industry asserts that the absence of any "significant" risk of leukemia at low-level benzene exposures was demonstrated at the hearing by "a series of epidemiologic studies of hundreds of thousands of workers exposed to low concentrations of benzene." API Br. at 14-15. But the Secretary analyzed each of those studies and found that because of gross deficiencies in the design of the studies, their results are meaningless. See Pet. App. 107a-112a, 123a-124a, 182a. As we now show, the Secretary's appraisal of the "negative studies" was well-founded.

a) *The Thorpe Study.* Industry places its primary reliance on a study conducted by Dr. John Thorpe, Associate Medical Director of Exxon Corporation. See API Br. at 15-16. But the Secretary found the Thorpe study to be invalid (Pet. App. 110a-111a); and that judgment was supported by the testimony of NIOSH (Tr. 745) and several expert witnesses. See, e.g., Tr. 914, 1200-1201 (Dr. Infante); Tr. 914-915 (Dr. Smith).[3]

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[2] In addition, the UNC study used an extremely inexact method for determining the department in which an employee was deemed to have worked. See Ex. 187.B-13 at 25. As a result, it is entirely possible that many of the workers whom the UNC study assumed had worked in Pliofilm operations had actually spent most of their time in other departments where benzene was not present. For these and other reasons, the UNC researchers certainly did not regard their study as demonstrating that low levels of benzene exposure pose no significant health risks. To the contrary, the study recommended that "[e]xposures to benzene should be maintained as far below the Threshold Limit Value [i.e., 10 ppm] as is possible." *Id.* at 35.

[3] See also the responses of Dr. Lamm and Dr. Tabershaw, testifying for respondent Manufacturing Chemists Association, to the questioning of Dr. Lloyd. Tr. 2661-2664.

Dr. Thorpe had almost no idea what proportion of the workers studied actually had been exposed to benzene, let alone how long they had been exposed (Tr. 2021-2022, 2025-2029). As was conceded by Dr. Steven Lamm, a witness for respondent Manufacturing Chemists Association ("MCA"), "there may well have been, within Dr. Thorpe's group, some subgroups which had exceedingly high rates of leukemia that he didn't identify in his analysis." Tr. 2664.[4]

An epidemiologic study which, like Dr. Thorpe's, is "diluted" by the inclusion of large numbers of unexposed workers can easily mask severe cancer risks. This is illustrated by a series of studies concerning carcinogenic coke oven emissions which demonstrate dramatically the danger of relying on a "diluted" study. The original coke oven studies were not limited to the employees who were actually exposed to the emissions from the ovens and at first did not show a significant excess incidence of cancer among the employees studied. But when the researchers went on to focus on a particular subgroup, top-side coke oven workers, who were so exposed, an enormous increase in the incidence

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[4] Industry quotes the statement of Dr. Robert Snyder, a witness for respondent American Iron and Steel Institute, that "using the most powerful statistical tools available and concentrating on the most highly exposed population of workers, it was not possible to detect a greater incidence of leukemia [in the Thorpe study] than in the population at large." API Br. at 15-16, n. 35, quoting Ex. 156-2 at 17. Industry implies that Dr. Snyder meant to indicate that the overall results of the Thorpe Study are such as to rule out the possibility that the workers included in the study who were actually exposed to benzene may have suffered a significant excess incidence of leukemia. But to the extent Dr. Snyder's statement could be so interpreted, he retracted it on cross-examination. When questioned regarding his statement, Dr. Snyder explained that in referring to "the most highly exposed population of workers," he was not referring to the particular subgroup of workers in the Thorpe study who were actually exposed to benzene; rather, he explained, "[p]eople who are working . . . in the petroleum industry [a]re exposed to a variety of chemicals and that is all it means." Tr. 3227-3228. Dr. Snyder further testified as follows:

• • •

of lung cancer was detected.[5] As was noted repeatedly during the benzene hearing, the coke oven emissions data present a classic example of how easily a severe risk to an exposed subgroup can be obscured by data concerning a group containing large numbers of unexposed workers. See, e.g., Tr. 1437-1438, 2329.[6]

In short, as the Secretary stated, "[t]he fundamental premise of any epidemiological investigation of the potential relationship of occupational exposure to an agent and observed health effects is . . . a careful definition of an exposed cohort." Pet. App. 124a. See also Pet. App. 182a.

Dr. Lloyd: But I wonder what your point is about the use of "powerful statistical tools," what that might add to the analysis.

Dr. Snyder: His data was incomplete, but within the framework of the data that he had here, trying to draw some conclusions based on the statistics he could apply, given that these are imperfect, and given the fact that we know he didn't have complete data, he tried to do the best he could with what he had, and that was the only point that I was trying to make here. Tr. 3292-3294.

Similarly, the statement in a paper by the National Academy of Sciences that the Thorpe study "seem[s] to indicate that there is not an outstandingly high incidence of leukemia in the workers studied" (Ex. 2-4 at ii, cited in API Br. at 16, n. 36) obviously refers to the entire group studied by Dr. Thorpe, not to the subgroup of workers who were actually exposed to benzene.

[5] See Ex. 113; Ex. 217.27.D. Largely as a result of these later studies, employee exposure to coke oven emissions is now regulated by an OSHA standard, which has been upheld in pertinent part by the Court of Appeals for the Third Circuit, *American Iron and Steel Institute* v. *OSHA*, 577 F.2d 825 (1978), *petitions for cert. pending*, Nos. 78-918, 78-919.

[6] Indeed, the concessions made by industry witnesses such as Dr. Lamm and Dr. Snyder regarding the "dilution" inherent in the Thorpe study came in response to the questions of Dr. William Lloyd, who was the principal author of the coke oven studies. See, e.g., Tr. 2664.

The Thorpe study, as the Secretary found, failed to comply with this threshold requirement. See Pet. App. 110a-111a.

Nor was the "dilution" problem the only defect in the Thorpe study. The Secretary cited several others. Pet. App. 110a. For example, Dr. Thorpe's method of determining the number of leukemia deaths suffered by the workers was highly inaccurate (Tr. 2015-2029, 2071, 2074-2075). Moreover, the study excluded altogether the workers who had terminated their employment early, and the medical history of retirees was not investigated with any accuracy. (Tr. 2023-2025). Workers who terminate their employment early, and also retirees, are known to exhibit a particularly high incidence of disease, and therefore any study which excludes those groups may severely understate the cancer risk which is actually present. In this regard the classic example is a series of British studies concerning vinyl chloride, in which the very great cancer hazard posed by that substance [7] was not evident until workers who had terminated their employment early were included in the studies. See Tr. 1200, 1438-1440. As Dr. Infante testified, by excluding such workers the Thorpe study is guilty of the very flaw which was highlighted by the British vinyl chloride studies. Tr. 1200.

In short, while Dr. Thorpe may not be "ashamed" of his study (Tr. 2021), the Secretary was right in regarding the study as casting no light on the question of the leukemia risk posed by low levels of exposure to benzene.

b) *The Tabershaw/Cooper Study.* The Tabershaw/Cooper Study, relied upon by industry (API Br. at 15) suffered from the same basic flaws as the Thorpe study, but to an even greater degree. As the Secretary emphasized, this study, involving 17 selected refineries, was designed to investigate the effects of exposure to hydrocarbons in general, not benzene. Pet. App. 108a. Dr. William Gaffey,

[7] Employee exposure to vinyl chloride is regulated by an OSHA standard which was upheld in *Society of the Plastics Industry, Inc.* v. *OSHA*, 509 F.2d 1301 (2d Cir.), *cert. denied*, 421 U.S. 992 (1975).

one of the authors of the report, testified that for all he knew, fewer than 10 percent of the workers studied may have been exposed to benzene. Tr. 1411; see also Tr. 1351, 1358, 1434. The Secretary properly concluded that "since no group of workers exposed to benzene was clearly identified, this study provides no relevant information as to the leukemogenic risk of exposure to benzene." Pet. App. 108a. Dr. Gaffey in effect admitted the correctness of the Secretary's conclusion when he was asked a question comparing his study to the "diluted" coke oven studies discussed above:

> Mr. Wagoner: What I would like to ask you is given the similarities between the two studies, could you possibly have within your study population, a smaller subsegment who had been exposed to benzene who are experiencing a risk factor of the order of magnitude similar to that found by Dr. Lloyd in the steel industry, and yet by studying it in the method that you have, you would have obscured or overlooked this risk?
> Dr. Gaffey: I cannot rule out that possibility. (Tr. 1438).

In addition, just as the Thorpe study had excluded workers who terminated their employment early, so did the Tabershaw/Cooper Study. As just noted, this method of proceeding obscures the leukemia risk posed by benzene to the workers studied by Dr. Gaffey and his associates. See Tr. 1438-1440. For these reasons, the Secretary's refusal to rely on the Tabershaw/Cooper study (Pet. App. 107a-108a) was well-founded.

c) *The Stallones Study.* The study by Dr. Reuel Stallones of Shell Oil Company workers (see API Br. at 15, referring to Ex. 115.C-2) rests on no better footing. As the Secretary noted "[a]gain, failure to correctly identify or define a benzene-exposed cohort limits the usefulness of this study." Pet. App. 111a. The study included *all* Shell employees, including office workers (see Tr. 2324-2325), and Dr. Stallones had to concede that "perhaps quite a large proportion [of the group studied] are not exposed to benzene."

Tr. 2302. Nor did Dr. Stallones have any idea as to the lengths of exposures involved. Tr. 2300. Moreover, 80% of the exposures monitored were below 1 ppm. Tr. 2296. Like the other "negative studies," the Stallones study excluded workers who left their employment early. Tr. 2298. Consequently, as was made clear by Dr. Stallones' responses to questions posed by Dr. Infante, no conclusions can be drawn from this study. See Tr. 2326-2331.

d) *The Steel Industry Studies.* It is remarkable that industry should claim to find significance in "a long-term mortality study of the steel industry," which, according to industry, "showed that coke oven and by-products facilities workers, exposed over the years to low concentrations of benzene, had not experienced any excess incidence of leukemia." API Br. at 15. For these are the very coke oven studies which demonstrate the error of drawing any conclusions regarding the risk posed by a chemical from a study which does not focus specifically on workers who are actually exposed to the chemical. (See pp. 5b-6b, *supra.*)

The coke oven studies, designed to determine the incidence of cancer (particularly lung cancer) resulting from coke oven emissions, did not seek to identify a group of workers exposed to benzene. Consequently, as Dr. Lloyd, the principal author of the studies, established by his questioning of the witnesses for the American Iron and Steel Institute, there is no way to tell from the coke oven studies what the incidence of leukemia may be among those steelworkers who are actually exposed to benzene. See Tr. 3315. And see generally Tr. 3300-3306, 3313-3315. In addition, the number of employees in the work area suggested by industry as most likely to include some benzene-exposed workers—the coke plant by-products area—was too small to permit any conclusions regarding the relationship between benzene and leukemia to be drawn in any event. See Tr. 3314. In short, as is apparent from Dr. Lloyd's examination of the AISI witnesses, industry's assertion that his studies demonstrate anything with respect to benzene is a gross misuse of the studies. The Secretary properly con-

cluded that "[g]iven the small numbers of observed and expected rates of leukemia, and in the absence of a study designed to assess coke oven worker exposure to benzene . . . it [is] inappropriate to rely on these studies. . . ." Pet. App. 111a.

Summary

As this review has shown, industry's contention that low levels of exposure to benzene involve risks which are non-existent or *de minimis* finds no support whatsoever in the epidemiologic studies upon which industry relies, and was properly rejected by the Secretary.

ADDENDUM C

An Additional Analysis of the Evidence Supporting the Secretary's Finding That It is Impossible to Derive a Meaningful Risk Assessment for Benzene, and in Particular, His Rejection of Dr. Wilson's Attempted Risk Assessment.

As shown in the reply brief, *supra* at 10-14, the Secretary found that there is no way to extrapolate from the risks attributable to high concentrations of benzene to predicted risks of benzene exposure at levels of 10 ppm and below; and the court of appeals did not upset that finding. The Secretary based his finding on inadequacies in the known data and in the hypothesized theories of extrapolation. Further, the Secretary specifically considered and rejected the handwritten extrapolation prepared by Dr. Richard Wilson, a physicist, which industry submitted in the rule-making proceedings, and which, notwithstanding the Secretary's rejection, industry presents to this Court.

We show herein that an examination of the Wilson testimony illustrates the correctness of the Secretary's finding that such extrapolations regarding the risks of exposure to benzene are invalid. As we show, Dr. Wilson's method was to ignore the gaps in the existing data or, where he acknowledged that such a gap existed, to fill it in with assumptions which were designed to understate the magnitude of the projected risk.

I.

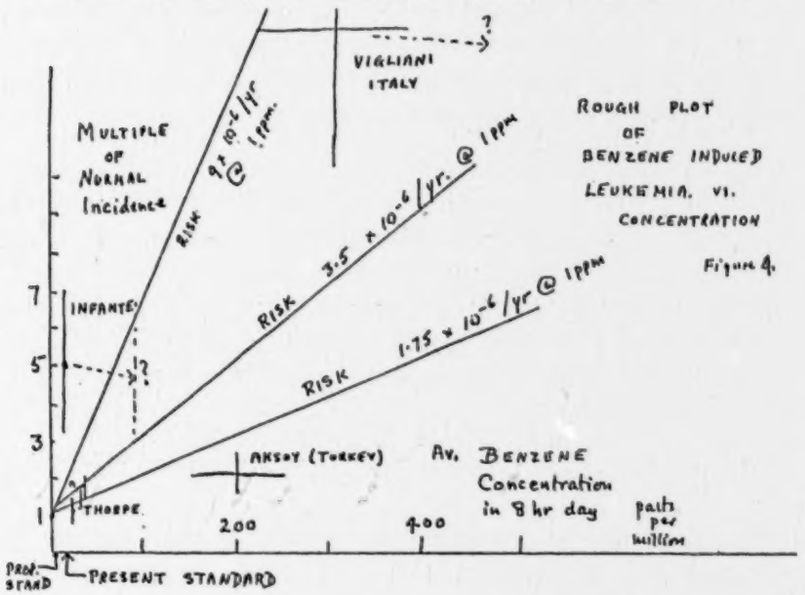
To construct an extrapolation from known points to unknown points, there must first be known points—certain dose-response points for benzene-leukemia must be identified as a predicate to any extrapolation of the response at other doses. A given "dose" of benzene is essentially a function of two factors: the *level* of benzene exposure and the *duration* of benzene exposure. Regular exposure to 1 ppm of benzene over 40 years is not the same dose of benzene as exposure to 1 ppm of benzene over a five year

period. The "response" to a given dose of benzene is the incidence of leukemia associated with that dose.

To select a starting point for his extrapolation, Dr. Wilson referred to four of the epidemiologic studies in the record: those of Drs. Infante, Vigliani, Aksoy and Thorpe. On a hand-written graph, reproduced in the margin,[1] Dr. Wilson recorded his understanding of the results of the four studies. As the graph shows, for each study Dr. Wilson recorded the exposure level he believed to have been involved, and the multiple of the leukemia incidence in the general population (i.e., the "risk factor") he believed to have been reported.[2]

But what Dr. Wilson recorded does not correspond to the

[1] Dr. Wilson's graph, which appears at App. 170, is as follows:



[2] On the graph, the horizontal axis plots benzene exposure levels and the vertical axis plots the risk factor. Each of the four studies is represented by a point on the graph, identified by the names of the four researchers. Vertical and horizontal lines extending out from each of the four points represent the range of uncertainty which Dr. Wilson believed to exist with respect to the risk factor and exposure levels involved in each study.

actual data produced by the studies. The data in fact, as the Secretary found, do not provide sufficient information to plot a dose-response curve. Dr. Wilson filled in the gaps in the data with assumptions which are not only unfounded but tend to greatly understate the risk of leukemia resulting from benzene exposure. We illustrate these points below by reference to Dr. Wilson's treatment of each of the factors involved in a dose-response analysis.

DOSE

A. *Duration.* Dr. Wilson did not even discuss the question of the duration of the benzene exposures involved in the four studies. In utilizing the studies for his extrapolation, he apparently assumed, erroneously, that the leukemia incidence reported in each study represents the risk resulting from benzene exposure spanning an *entire working life* at the levels involved in the study. See App. 89. In actuality, however, the duration of the exposures involved in each of the studies is highly uncertain, and may well have been quite short.

For example, the group of employees studied by Dr. Infante included every white male employee who worked *at any time* during the years 1940 to 1949 on a job which was thought to entail exposure to benzene at the plants in question. Ex. 40 at 5. It is impossible to estimate what the actual durations of exposure may have been. A later study involving the same plants suggests that workers may have moved frequently from jobs involving benzene exposure to jobs involving no exposure, and vice-versa. See Ex. 187.B-13 at 25. Hence the aggregate exposures reflected in the Infante study may have been short. Similarly, in both the Vigliani and Aksoy studies it is likely that the duration of exposure varied greatly from employee to employee, with many employees exposed for only a few years, and few if any employees exposed for more than fifteen or twenty years. See Pet. App. 100a-101a.[3]

[3] As for the Thorpe study, the Secretary properly found that study to be meaningless (see Addendum B, pp. 4b-5b), and we therefore do not consider it here.

A § 6(b)(5) standard must be geared to protecting an employee who "has regular exposure to the hazard dealt with by such standard for the period of his working life." To provide the information necessary under § 6(b)(5), an extrapolation must show the risk of leukemia associated with a given level of exposure over the course of an employee's entire working life: some thirty-five to fifty years. The data here do not allow for any such extrapolation. Dr. Wilson simply willed away that problem by falsely assuming that the epidemiologic studies represent the effects of lifetime exposures. His "risk assessment" is therefore not only meaningless but necessarily understated to a significant, albeit unknowable degree.

B. *Level.* In constructing his graph, Dr. Wilson had to determine the levels of exposure which had produced the leukemia incidence reported in each study. But as the Secretary found, enormous uncertainty surrounds that question. See, e.g., Pet. App. 182a. For example, in the case of the Infante study the evidence indicates that at some times the benzene concentrations at the plants in question may have been as low as 0 to 15 ppm, while at other times they may have been much higher. And with respect to that study the Secretary found:

> . . . [A]ny conclusion regarding the actual individual time-weighted average exposure is speculative. Because of the lack of definitive exposure data, OSHA cannot derive any conclusions linking the excess leukemia risk observed with any specific exposure level.

Id. at 105a.

Consequently, as Dr. Douglas Smith of NIOSH testified, it is impossible to determine what level of exposures actually caused the observed leukemia deaths reported by Dr. Infante:

> A lot of emphasis has been placed upon the fact that individuals could have been exposed to these very high levels that were basically extremes and as has been stated, it is possible but we don't know any more than

> to speculate. By the same token, one can speculate also that they were exposed to the low ranges as well, and that effects could have occurred from the low ranges.

Tr. 996.

Dr. Bernard Goldstein of the New York University Medical Center made the same point with respect to all the epidemiologic studies of benzene exposure: "[W]e really have no information as to the exposure level of any of the individuals who have developed acute leukemia." Ex. 75 at 2.

Nevertheless Dr. Wilson's graph interprets each of the epidemiologic studies as showing a particular incidence of leukemia resulting from a particular exposure level (or in some cases, a narrow range of exposure levels). Thus, in this respect as well, the Wilson risk assessment rests on an assumption contrary to fact and to the Secretary's findings.

RESPONSE

Dr. Wilson did not take into account the possibility that the studies may have greatly underreported the actual incidence of leukemia in the workers studied. Yet Dr. Infante was unable to determine whether or not twenty-five percent of the workers included in the group he studied had died, and for purposes of the study he assumed that every one of them was alive. Among the other seventy-five percent of the workers, the additional leukemia cases discovered by Dr. Sakol among the employees studied by Dr. Infante indicate that Dr. Infante's method of determining the causes of death among the workers resulted in his missing a significant number of cases of leukemia.[4] Also, many of

[4] Industry erroneously asserts, API Br. at 11, n. 19, that the additional leukemia deaths found by Dr. Sakol do not indicate that Dr. Infante's study underestimated the risk of leukemia. That assertion is contrary to the testimony of the authors of the Infante study. See Tr. 768-772, 903-905.

the workers studied were still alive, and thus their eventual cause of death cannot be known.[5]

As a result of these and other factors, Dr. Infante's own assessment was that his study had "tremendously underestimated the true risk of leukemia in this population. . . ." Tr. 768; see also Tr. 874-875. Edward Baier, then Deputy Director of NIOSH, agreed with that assessment. Tr. 747. And Dr. Sakol's conclusion was that the Infante study "grossly underestimates the incidence" of leukemia in the workers studied. Tr. 314.

Similarly, by Dr. Aksoy's own account, the Aksoy study substantially understates the actual incidence of benzene leukemia among the workers he studied (Ex. 60 at 1-2). And the Thorpe study was designed in a manner which tends so patently to understate the risk of benzene leukemia that the Secretary properly found that study to be meaningless. See Addendum B, pp

Nevertheless, in performing his risk assessment Dr. Wilson did not take into account the likelihood that all of the epidemiologic studies may seriously underestimate the risk of benzene leukemia. To the contrary, as we next discuss, he arbitrarily chose to assume that the Infante and Vigliani studies had greatly *overstated* the risk.[6]

For the reasons just stated, Dr. Wilson's "risk assessment," based on the studies of Drs. Infante, Vigliani, Aksoy and Thorpe, would contain fatal deficiencies even if the four studies were consistent in their results. But in fact the results of the four studies are not consistent, and Dr. Wilson therefore found it necessary "to make sense out of this highly discorded [sic] set of data." App. 88. In order to "make sense" out of the data, Dr. Wilson chose to assume that the Infante data had *overstated* the risk to the population Dr. Infante had studied,[7] while in reality, as we have shown, the Infante data were almost certainly *understated*. Dr. Wilson also assumed that the studies of Dr. Vigliani were overstated.[8] As a physicist who lacked any special ability to determine the validity of any of the epidemiologic studies in the record, Dr. Wilson did not reach his assessment of the Infante and Vigliani data on the basis of any expert evaluation of that data. Rather, he believed that the results reported by Drs. Infante and Vigliani should be discounted merely because they appeared to be inconsistent with the studies of Dr. Aksoy and Dr. Thorpe—this despite the fact that the Aksoy data, even according to Dr. Aksoy, underestimate the risk, and that the Thorpe study contains such manifest flaws that the Secretary properly rejected its findings. See p. 3c, n. 3, *supra*.

Dr. Wilson's arbitrary and erroneous decision to discount the results of the Infante and Vigliani studies led him to base his calculations on an assumed dose-response curve, which he described as "slightly better than a guess" (App. 92), and which predicts a risk much smaller than the risk which he would have predicted had he not regarded the Infante and Vigliani data as overstated.[9]

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[5] The foregoing facts appear at Pet. App. 102a-103a, 104a-105a, 107a. See also the material cited in our opening brief at 9-10, n. 4.

[6] An additional flaw in Dr. Wilson's response "calculation" is the following: in utilizing the four studies Dr. Wilson made no allowance whatsoever for the critical fact that susceptibility to benzene leukemia varies among different individuals and groups. See the reply brief, *supra* at p. 12, n. 15. Dr. Wilson thus simply disregarded a consideration which introduces uncertainties of unknown dimensions into any attempted risk assessment for benezene.

What is more, while Dr. Wilson made the peculiar assumption that for each case of benzene leukemia there will be an additional case of some other form of cancer, and he therefore multiplied his dose-response projections by a factor of two (App. 171), he did not take into account any of the known benzene-related risks other than cancer, such as aplastic anemia. Any attempt to factor in these additional risks would involve the same problems as are presented with respect to assessing the leukemia risk. See, e.g., Pet. App. 82a-98a, 160a.

[7] See App. 171, 88, 92-93.

[8] *id.* at 88.

[9] The extent to which Dr. Wilson discounted the Infante and Vigliani data can be seen by examining Dr. Wilson's graph (see note 1, *supra*).

II.

The Secretary found that apart from inadequacies in the data, there is no satisfactory theory of extrapolation from known carcinogenic effects of a substance at high exposure levels to projected carcinogenic effects of the substance at lower exposure levels. Dr. Wilson chose to estimate the risks of benzene exposure at low levels by drawing a *linear* dose-response curve, *viz.* he assumed that the risks are directly proportional to the level of exposure. See note *supra*. But Dr. Wilson conceded that the actual dose-response curve could well be very different from the linear extrapolation he employed (Tr. 2719-2720), and that "any dose-response curve is possible." App. 93.

Dr. Wilson described the linear extrapolation technique as a "fairly prudent and slightly conservative" assumption (App. 89). But Dr. Lloyd suggested that at high levels of benzene exposure, the number of diagnosed leukemias may be reduced by the fact that many workers may die of other benzene-induced diseases such as aplastic anemia before the onset of leukemia, while at low levels this phenomenon

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In constructing dose-response curves on his graph, Dr. Wilson assumed that such curves would be linear, i.e., that risk is directly proportional to exposure. Consequently, the dose-response curve attributable to any given study under Dr. Wilson's system would consist of a line between the point which represents the results of that study and the point on the vertical axis of the graph which represents a normal incidence of leukemia (i.e., a risk factor of one) at zero exposure. (On the graph, the latter point is where the three lines marked "risk" intersect).

The dose-response curve which Dr. Wilson selected to predict the risk of benzene leukemia is the line marked "1.75 x 10^{-6}/yr. @ 1 ppm" on the graph (App. 171). On that dose-response curve, a risk factor of 7 would occur at approximately 550 ppm. Yet on his graph, Dr. Wilson recorded the Infante data as showing a risk factor as high as 7 at exposures somewhere between *10 ppm and 100 ppm*. Similarly, Dr. Wilson plotted the Vigliani data as showing a risk factor of approximately 15 at exposures of approximately 300 ppm (and the risk factor actually reported by Dr. Vigliani was 20, see Pet. App. 100a); yet the dose-response curve selected by Dr. Wilson shows a risk factor of only *4* at that level of exposure.

may not be present to the same degree. If that were the case, a linear extrapolation would understate the leukemia risk at low levels of exposure, and a curve rising steeply at low doses and flattening out at the top would be accurate. Dr. Lloyd stated, based on his experience, that similar circumstances have been found to exist with respect to beryllium and asbestos, and he asked Dr. Wilson whether the same might not be true of benzene, "[p]articularly in light of Dr. Aksoy's report with so many of the shoemakers dying from their blood dyscrasia [a non-malignant disorder]." App. 93. Dr. Wilson replied that he could not rule out that possibility. *Ibid.*

The possibility discussed by Dr. Lloyd is only one of many factors which indicate that the "linear hypothesis" may lead to an underestimate of the risk of low-level benzene exposures. As a commentator has observed, "[u]ntil we have a detailed understanding of the molecular mechanisms of carcinogenesis, we have no basis for saying whether the 'linear hypothesis' assures an adequate margin of safety." Lovins, *Cost-Risk-Benefit Assessments in Energy Policy*, 45 Geo. Wash. L. Rev. 911, 922 (1977).

III.

Finally, even if a meaningful dose-response curve could be constructed, an additional problem would remain. The actual number of deaths which the standard would prevent cannot be determined in the absence of information as to the number of workers who, were the permissible exposure level not reduced below 10 ppm, would be exposed at each level between 10 ppm and 1 ppm. The data on this point are very imprecise, and Dr. Wilson admitted that his calculations were based on an assumption that without the standard now under review, workers would be exposed to 3 ppm of benzene. This assumption surely understates the extent to which the standard would reduce exposures, and therefore leads to an underestimate of the health benefits which would result from the standard. As Dr. Wilson conceded (App. 90):

"I tried to [determine] . . . who is exposed to what. . . ., but I didn't find it. * * * * So I made a very rough guess that they were three parts per million.

Dr. Wilson further conceded that this "guess" was based on at least one inaccurate assumption (*Ibid.*):

MS. KALARIS: I believe you stated that only a few 100 people would be regularly exposed to 10 ppm of benzene concentration. Can you explain the basis of that statement?

DR. WILSON: That is maybe incorrect. It came out of a page in this report here, and again, they were vague on this particular question. Therefore, I am a little vague on it. Probably, as I was thinking about it last night, I think a few hundreds; it is probably closer to 1,000 than 100, but I really don't know."